



APR 25 1997

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

4/19

David J. Levy, Ph.D.
Glaxo Wellcome, Inc.
Patent Counsel
Five Moore Drive
Research Triangle Park, NC 27709

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,883,812

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,883,812, which claims a method of use of the human drug product FLOLAN® (epoprostenol sodium)(prostacyclin sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,347 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Applicant is required to elect a single patent to be extended under 35 U.S.C. § 156 within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to these time periods.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of April 5, 1996 (61 Fed. Reg. 15,265). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\ &= \frac{1}{2} (5,357 \text{ days} - 3,803) + 570 \text{ days} \\ &= 1,347 \text{ days (3.7 years)}\end{aligned}$$

Since the regulatory review period began July 1, 1979, before the patent issued November 28, 1989, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From July 1, 1979 to November 28, 1989 is 3,803 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $5,357 - 3,803 = 1,554$ days.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the five year limitation of 35 U.S.C. § 156(g)(6)(A) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of

time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,347 days.

It is noted that applicant, Glaxo Wellcome Inc., has also filed an application for patent term extension of U.S. Patent No. 4,338,325, which is owned by The Upjohn Company, based upon the regulatory review of the product FLOLAN®. No more than one patent may be extended for a regulatory review period of a single product. 35 U.S.C. 156(c)(4). Normally, when applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. However, applicant has stated that U.S. Patent No. 4,883,812 is elected, unless found ineligible for patent term extension. Accordingly, in the absence of a contrary election by applicant within ONE MONTH of the date of this notice, the Commissioner will issue a certificate of extension, under seal, for a period of 1,347 days. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,883,812
Granted	:	November 28, 1989
Original Expiration Date	:	September 3, 2002
Applicant	:	Salvador Moncada
Owner of Record	:	Glaxo Wellcome Inc.
Title	:	Treatment of Hypertension Using Prostacyclin
Classification	:	514/469
Product Trade Name	:	FLOLAN®
Term Extended	:	1,347 days
Expiration Date of Extension	:	May 12, 2006

Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.

Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: FLOLAN®
FDA Docket No.: 95E-0419